Remarks

The various parts of the Office Action are discussed below under related headings.

Brief Description of the Drawings

The specification was objected to for lack of a brief description of the drawings. As required, a brief description of the drawings has been added. Applicants' representative notes that the brief description of the drawings includes language already present in the application as filed and, as such, does not introduce new matter into the application.

Objection to Specification and Claim Rejection - 35 USC § 112, 1st ¶

The specification was objected to and claims 1-15 were rejected for want of an enabling disclosure. According to the Examiner, the manner of developing an inversely planned radiotherapy plan has not been taught in the specification. Indeed, the specification does not describe at length such a process as the same was known in the art at the time the application was filed. Methods of developing inversely planned radiotherapy plans existed and were available to persons skilled in the art at the time the application was filed.

In particular, one skilled in the art knew at the time of the priority applications how to develop an inversely planned radiotherapy plan. This is evidenced by the four documents attached hereto as Exhibits 1-4, all of which use "inverse planning" as a term of art.

In addition, the Examiner's attention is directed to U.S. Patent No. 5,373,844 to Smith et al., entitled INVERSE TREATMENT PLANNING METHOD AND APPARATUS FOR STEREOTACTIC RADIOSURGERY, which was cited by the applicant in the Information Disclosure Statement filed on July 24, 2002. The '844 patent provides a description of "inverse treatment planning."

In accordance with the attached documents, the term of art, "inverse planning," means that, with the help of volume-dose histograms, the planner, as a very first step, defines a result he/she wishes to achieve and then uses the computer to see if and how close he/she can come to this result. To this end, in a first step, the planner can provide the computer with an input resulting in 100% of a lesion receiving 100% of the radiation dose, while the surrounding healthy tissue, e.g., a risk organ, receives 0% of the radiation dose. A computer for radiation planning then calculates to what extent this

result is possibly achievable with the inherent parameters of the system (radiation apparatus, position and form of the lesion). With such input parameters as given above, one will soon come to the result that such an ideal plan is hardly computable. At this point, the present invention takes effect in postulating that input parameters for the computer of an older, calculatable plan could help to make the calculation of a new plan possible in an acceptable time.

The calculation of such a plan in the inverse way is rather difficult and time consuming. In this connection, the present invention, rather than creating a new and better plan, aids in the calculation of a plan that works more efficiently.

To further clarify the meaning of claim 1, applicant has amended claim 1. The changes are for clarification of the claimed subject matter and are not believed to raise new issues, thereby placing the application in better condition for allowance and/or appeal.

In view of this, it is respectfully submitted that the application is enabling. Therefore, the objection to the specification and rejection of claims 1-15 should be withdrawn.

Claim Rejection - 35 USC § 112, 2nd ¶

The claims were rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because the meaning of "inversely planned radiotherapy plan" is considered unclear. In view of the foregoing discussion and Exhibits 1-4, "inversely planned radiotherapy plan" is a term of art with well-known limitations. Accordingly, the rejection should be withdrawn.

With regard to the Examiner's comments that, "[a]pparatus claims 13 and 14 improperly depend on method claim 1," applicants respectfully disagree with this conclusion and direct the Examiner's attention to MPEP 608.01(n), which states *inter alia* "the test for a proper dependent claim is whether the dependent claim includes every limitation of the parent claim." In particular, MPEP 608.01(n) instructs that, "[t]he fact that the independent and dependent claims are in different statutory classes does not, in itself, render the latter improper." For example, "if claim 1 recites a method of making a product, a claim for a product made by the method of claim 1 could be a proper claim."

The key inquiry in determining whether a dependent claim is proper is "whether the dependent claim includes every limitation of the claim from which it depends . . . or

in other words that it shall not conceivably be infringed by anything which would not also infringe the basic claim."

It is respectfully submitted that claims 13 and 14 are proper dependent claims because they each include every limitation of independent claim 1. Accordingly, the rejection should be withdrawn.

Claim Rejections - 35 USC § 103

The Examiner has rejected claims 1-4 and 7-15 as being unpatentable over Swerdloff U.S. Patent No. 5,661,773 and claims 5-6 as being unpatentable over Swerdloff in combination with WO 97/40766. As will become apparent from the following discussion, the Swerdloff patent teaches a method that is fundamentally different from the claimed method.

As understood, Swerdloff somehow makes a treatment plan and then carries out that treatment. During the treatment, radiation errors are determined and then, based upon the determined errors, a next treatment is planned.

On page 4 of the Office Action, the Examiner asserts that Swerdloff helps the planner react to certain changes which have occurred between the present planning step and the one before and that this teaching renders the present invention obvious. Applicants' representative respectfully submits that the Examiner's reliance on Swerdloff is misplaced.

Of course, any treatment plan should take care of positional changes of the lesion to be treated, but the present invention does not primarily deal with this problem. **The present invention helps to identify input parameters for the inverse planning which rapidly lead to an acceptable result.** When such parameters are found, the objective of the present invention has been fulfilled.

Thereafter, the computer calculates the plan, taking into account an organ shift or the like, but this is not what the present invention deals with in general. The correction of errors as it is done in Swerdloff may be comparable with the calculation made by the computer to compensate for organ shifts, but, in the scheme of the present invention, this happens after the step of finding and inputting initial parameters for the inverse planning. **Therefore, Swerdloff deals with a part of the planning method which only takes place after the key steps of the present invention have already been carrier out.**

Moreover, applicants' method as set forth in the claims involves producing or updating an inversely planned radiotherapy plan. The claimed method does not rely on the result of the actual treatment. Instead, applicants' method as claimed assumes the dose distribution has been set sufficiently good in the first inverse plan, and then calculates a new plan on the basis of the planned results of the first plan. The new up-to-date plan is adapted, for example, to new CT-data. Applicants' claimed method does not require a determination to be made of any errors that may have occurred during the earlier treatment.

That is, Swerdloff bases his second plan upon determined errors in the first plan while the applicants' method as claimed does not require determination of such errors but instead saves a lot of effort and time by reusing the planning data of the first plan instead of newly establishing another plan from scratch. The second plan is adapted from the first plan by taking into account, for example, organ shifts as determined by a new CT-scan. Swerdloff does not trust his original plan. Instead, it is assumed that errors will occur and Swerdloff seeks to correct these errors by building a completely new plan, which is exactly the effort the present invention avoids. In this regard, the Examiner's attention is directed to column 3, lines 57 to 61 of the Swerdloff patent, which reads:

> Where a treatment error (i.e. over or under radiation) has occurred, the error can be noted using the human interface and can be used to alter desired dose maps during later therapy sessions to compensate for the errors.

Also, in column 2, lines 51 to 63, it is said:

> After different irradiation zones within a tomographic image have been identified, the interface allows the operator to specify various radiation doses for each irradiation zone, to run a test simulation which takes into account radiation scatter during a therapy session to derive a theoretical pre-radiation dose map based on the doses specified by the operator, to easily change the doses specified by the operator as a function of the theoretical pre-radiation dose map that results, to verify radiation dose after a therapy session, and to plan for subsequent therapy sessions based on dose delivered during previous therapy sessions.

The last part, namely "to plan for subsequent therapy sessions based on dose delivered during previous therapy sessions," confirms that such technique is intended to take into account the actually applied dose (i.e. the error therein) for future planning.

Moreover, dosage-volume histograms, the basis for the planning according to the present invention as claimed, are nowhere mentioned in the Swerdloff patent. For this additional reason, Swerdloff does not fairly teach or suggest applicants' invention as claimed.

WO 97/40766 does not overcome above-noted fundamental deficiencies of the Swerdloff reference as a teaching reference vis-a-vis the claimed subject matter. Thus, the applied references, taken alone or together, do not lead the skilled person to applicants' method as set forth in the claims.

As a final item, in the last response, filed on July 24, 2002, applicants directed the Examiner's attention to the PTO-1449 form listing the art cited in the International Search Report. The Examiner indicated consideration of four of the documents that were submitted. However, the Examiner drew a line through DE 199 12 708 for an unknown reason. The Examiner did write something in the margin, but it was partly cut off on the copy attached to the Office Action.

The applicants renew their earlier request for the Examiner to clarify why the German patent document was crossed off. It is noted that the relevance of the German patent document is indicated in the European Search Report, a duplicate copy of which was attached to the July 24, 2002 response. In particular, the German patent document was cited as being of general background interest in respect of claims 4 and 7, with specific reference being made to column 3, lines 18-27, and column 4, lines 17-38.

This application is now believed to be in condition for allowance and an early action to that effect is earnestly solicited.

Respectfully submitted,

RENNER, OTTO, BOISSELLE & SKLAR, LLP

By Jason A. Worgull

Jason A. Worgull, Reg. No. 48,044

1621 Euclid Avenue
Nineteenth Floor
Cleveland, Ohio 44115
(216) 621-1113

A. Clean Version of Replacement Paragraph/Section/Claim with Instructions for Entry

Please amend the application as follows:

In the Specification:

Please add the following paragraphs before the paragraph beginning on page 5, line 4:

Brief Description of the Drawings

Figure 1 illustrates a pair of exemplary dosage-volume histograms for left and right optic nerves to be used in accordance with the present invention;

D1 Figure 2 illustrates an exemplary dosage-volume histogram for a target volume to be used in accordance with the present invention;

Figure 3 illustrates a pair of exemplary dosage- volume histograms for the target volume (left) and the brain stem (right) corresponding to a calculated inverse plan to be used in accordance with one embodiment of the present invention;

Figure 4 is a diagrammatic illustration of a computer tomograph system including a calibration phantom for use in conjunction with the present invention; and

Figure 5 is a diagrammatic illustration of a computer tomograph system used to detect the position of a patient for use in conjunction with the present invention.

In the Claims:

Please substitute the following amended claims for those of the same number that are presently pending:

1. A method for producing or updating an inversely planned radiotherapy plan for fractionated radiation exposure of a patient, wherein an up-to-date radiotherapy plan is calculated using volume-dose histograms, the up-to-date radiotherapy plan being at least partly calculated on the basis of an already existing, approved, older plan for the same patient, the patient being subjected to an imaging method before each radiotherapy session over a duration of the fractionated radiation exposure, and wherein the calculation of the up-to-date radiotherapy plan is carried out using new image data created thereby.

B. Version with Markings to Show Changes Mad

Please amend the application as follows:

In the Specification:

New paragraphs added before the paragraph beginning on page 5, line 4:

Brief Description of the Drawings

Figure 1 illustrates a pair of exemplary dosage-volume histograms for left and right optic nerves to be used in accordance with the present invention;

Figure 2 illustrates an exemplary dosage-volume histogram for a target volume to be used in accordance with the present invention;

Figure 3 illustrates a pair of exemplary dosage- volume histograms for the target volume (left) and the brain stem (right) corresponding to a calculated inverse plan to be used in accordance with one embodiment of the present invention;

Figure 4 is a diagrammatic illustration of a computer tomograph system including a calibration phantom for use in conjunction with the present invention; and

Figure 5 is a diagrammatic illustration of a computer tomograph system used to detect the position of a patient for use in conjunction with the present invention.

In the Claims:

1. (Twice Amended) A method for producing or updating an inversely planned radiotherapy plan for fractionated radiation exposure of a patient, [~~characterised in that~~] wherein an up-to-date radiotherapy plan is calculated using volume-dose histograms, the up-to-date radiotherapy plan being at least partly calculated on the basis of [~~the results~~] an already existing, approved, older plan for the same patient, the patient being subjected to an imaging method before each radiotherapy session over a duration of

the fractionated radiation exposure, and wherein the calculation of the up-to-date radiotherapy plan is carried out using new image data created thereby.

2. The method as set forth in claim 1, wherein pre-set values for calculating the inverse radiotherapy plan are determined from the results of a previously calculated plan.

3. The method as set forth in claim 1, wherein the patient is subject to an imaging method more than once over the duration of fractionated radiation exposure.

4. The method as set forth in claim 1, wherein the patient is subject to an imaging method before each radiotherapy session, wherein only a specified, defined area comprising the target volume is detected.

5. The method as set forth in claim 3, wherein the position of the patient relative to the imaging device is detected outside the region of the patient being imaged by the imaging device by the use of locating markers.

6. The method as set forth in claim 5, wherein the system for locating the markings is calibrated relative to the imaging device, such that the position of the markers can be determined relative to a data set recorded by the imaging device.

7. The method as set forth in claim 1, wherein a data set comprising the target volume is supplemented by automatic fusion with data from an older, larger volume data set, in order to obtain all the data necessary for calculating the dosage.

8. The method as set forth in claim 1, wherein the difference between the results of a new radiotherapy plan as compared to a previous plan are automatically quantified and, if the difference is within a previously specified tolerance range, the new plan is automatically qualified as an approved plan.

9. The method as set forth in claim 1, wherein, for transferring a radiotherapy plan onto a more recent planning data set, the position and form of a target volume and the organs to be protected are fully or partly adopted automatically into the new plan from the old plan.

10. The method as set forth in claim 9, wherein the information to be adopted into the new plan is transferred by means of a three-dimensional fusion of the contours, drawn in by hand, onto the layers or voxels of a new data set.

11. The method as set forth in claim 10, wherein fusion involves a graphic elastic morphing method of the information to be fused.

12. The method as set forth in claim 9, wherein an image detection plane of an imaging device, with the aid of which the planning data set is to be updated, is determined in an image recording range by introducing a calibration phantom comprising markings which can be detected both by image detection and by an external tracking system, wherein a spatial relationship with the patient markings which are not detected by image detection is produced for the images detected.

13. A computer programmed to perform the method set forth in claim 1.

14. A computer program storage medium comprising a program which, when running on a computer, performs the method set forth in claim 1.

15. The method as set forth in claim 3, wherein the imaging method is a CT or MR image recording method.